K001615

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HUNTER SCIENTIFIC LIMITED

# 510(k) Summary

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| **Date Prepared** | May 10th 2000 |
| **Submitted by:** | Hunter Scientific Ltd |
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| **Contact person:** | Mark Rawe |
| **Telephone:**<br>**Facsimile:** | +44 (0)1799 541 688<br>+44 (0)1799 541 703 |
| **Classification Name:** | Assisted Reproduction Microtools (CFR#884.6130) |
| **Common/ Propriety Names:** | Intracytoplasmic Sperm Injection Pipettes<br>Spermatid ICSI Micropipettes<br>Holding Pipettes<br>Zona Drilling Pipettes<br>Partial Zona Dissection Pipettes<br>Transfer Pipettes |
| **Device Name:** | Hunter Scientific Injection Pipettes<br>Hunter Scientific Holding Pipettes<br>Hunter Scientific Transfer Pipettes<br>Hunter Scientific Macro ICSI Pipettes<br>Hunter Scientific Partial Zona Dissection Pipettes<br>Hunter Scientific Zona Drilling Pipettes |

## Substantial Equivalence:

The Hunter Scientific microtools have the same intended use as the predicate devices, the Cook pipettes: to micromanipulate, hold or transfer human gametes or embryos for assisted hatching, ICSI, or other assisted reproduction methods. The Hunter Scientific injection pipettes also have the same indications for use as the predicate devices manufactured by Cook: the Intracytoplasmic Sperm Injection (ICSI) Micro Injection Pipettes are used for the intracytoplasmic single sperm injection of oocytes; the Holding Pipettes are used to hold the oocyte in position with the application of suction during single sperm injection with the micro-injection pipette. The Assisted Hatching and Zona Drilling pipettes are used to make a hole in the zona pellucida to enable embryo assisted hatching.

The Hunter Scientific pipettes are very similar to the Cook pipettes except for:

1) All Hunter Scientific ICSI pipettes are manufactured without a spike.

2) The dimensions of the inside and outside diameters, the lengths, bevels and angles may differ slightly. These small differences do not affect the safety or effectiveness of these devices in any way.

## Intended Use Statement

The Hunter Scientific Intracytoplasmic Sperm Injection (ICSI) Micro-Injection Pipettes are used for the intracytoplasmic single sperm injection of oocytes. The holding pipettes are used to hold the oocyte in position with the application of suction during single sperm injection with the microinjection pipette. The transfer pipettes are used to transfer and sort spermatazoa. The Zona Drilling Pipettes are used in conjunction with an acid solution to make a hole in the zona pellucida to assist the embryo in hatching. The Partial Zona Dissection pipettes are used to mechanically pierce a hole in the zona pellucida to assist the hatching of the embryo.

## Indications for Use

The Hunter Scientific pipettes are intended for use to micromanipulate, hold or transfer humane gametes or embryos for assisted hatching, ICSI, or other assisted reproduction methods.

## Description of Devices

The Hunter Scientific Intracytoplasmic Sperm Injection (ICSI) Micro-Injection Pipettes and Holding Pipettes are used in conjunction with a micromanipulator; this apparatus provides all movements and suction for the movement and positioning of the gametes.

**The ICSI Pipettes** enable the intracytoplasmic injection of a single sperm into an oocyte. The tip of the ICSI pipettes is beveled to provide less resistance when breaching the oocyte wall.

**The Holding Pipettes** are utilized to hold the oocyte in a stable position during this injection process. The holding pipettes are fire polished at the tip so as not to cause abrasion damage to the zona pellucida. There are two types of holding pipette, these are Biopsy holding pipettes and ICSI holding pipettes.

**The Macro Intracytoplasmic Sperm Injection Pipettes** (Macro ICSI) are used to enable the intracytoplasmic injection of a single macrocephalic sperm into an oocyte. The tip of the Macro ICSI pipettes is beveled to provide less resistance when breaching the oocyte wall. This pipette is a larger version of the ICSI pipette.

**The Zona Drilling Pipettes** are used in conjunction with an acid solution to erode a hole in the zona pellucida. This may be used to assist the hatching of the embryo or to enable blastomere removal.

**The Partial Zona Dissection Pipettes** are used to mechanically pierce a hole in the zona pellucida. This is used to assist the hatching of the embryo. It is essentially a spiked pipette.

**The Transfer Pipettes** are used when searching for spermatazoa from the macerate of cells supplied from a testicular biopsy. They are also used to transfer and sort spermatozoa.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 8 2000

Mr. Mark Rawe
Hunter Scientific Limited
Unit 1; Priors Hall,
Widdington
Saffron Walden, Essex, CB11 3SB
UNITED KINGDOM

Re: K001615
Leonard Assisted Reproduction Microtools-Pipettes
Dated: May 10, 2000
Received: May 25, 2000
Regulatory Class: II
21 CFR 884.6130/Procode: 85 MQH

Dear Mr. Rawe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

K001615

## Indications for Use

The Hunter Scientific **Intracytoplasmic Sperm Injection (ICSI) Micro-Injection Pipettes** are used for the intracytoplasmic single sperm injection of oocytes.

The Hunter Scientific **Holding Pipettes** are used to hold the oocyte in position with the application of suction during single sperm injection with the micro-injection pipette.

The Hunter Scientific **Transfer Pipettes** are used when searching for spermatozoa from the macerate of cells supplied from a testicular biopsy. They are also used to transfer and sort spermatozoa.

The Hunter Scientific **Macro Intracytoplasmic Sperm Injection Pipettes** MACRO ICSI) are used to enable the intracytoplasmic injection of a single macrocephalic sperm into an oocyte. The tip of the Macro ICSI pipettes is beveled to provide less resistance when breaching the oocyte wall. This pipette is a larger version of the ICSI pipette.

The Hunter Scientific **Partial Zona Dissection Pipettes** are used to mechanically pierce a hole in the zona pellucida. This is used to assist the hatching of the embryo. It is essentially a spiked pipette.

The Hunter Scientific **Zona Drilling Pipettes** are used in conjunction with an acid solution to erode a hole in the zona pellucida. This may be used to assist the hatching of the embryo or to enable blastomere removal.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001615

Prescription Use ✓
(Per 21 CFR 801.109)